K061793

AUG - 7 2006

510(k) Summary for the
Dimension Vista™ IRON Flex® reagent cartridge

A. 510(k) Number:

B. Analyte: Total iron

C. Type of Test: Quantitative

D. Applicant:
Manufacturer: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101

Contact: Andrea M. Tasker, Regulatory Affairs and Compliance Manager
(302) 631-9454

Date of Preparation: June 23, 2006

E. Proprietary and Established Names:
Dimension Vista™ IRON Flex® reagent cartridge

F. Regulatory Information:
1. Regulation section: 21 CFR §862.1410 Iron (non-heme) test system

2. Classification: Class I

3. Product Code: JIY

4. Panel: Chemistry (75)

G. Intended Use:
1. Intended for Use:

The Iron method for the Dimension Vista ™ system is an *in vitro* diagnostic test intended to quantitatively measure iron in human serum and plasma.

2. Indications for Use:

The Iron method for the Dimension Vista ™ system is an *in vitro* diagnostic test intended to quantitatively measure iron in human serum and plasma. Iron measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia and other disorders of iron metabolism.

3. Special condition for use statement(s): none

4. Special instrument Requirements: Dimension Vista ™ system

H. Device Description:
The Dimension Vista™ IRON Flex® reagent cartridge is an in vitro diagnostic device that consists of prepackaged reagents in a plastic eight well cartridge for use on the Dade Behring Dimension Vista ™ system for the quantitative determination of iron in serum and plasma.

I. Substantial Equivalence Information:
1. Predicate Device: Dimension® Iron Flex® reagent cartridge (IRON- DF85)

2. Predicate K Number(s): K060264

3. Comparison with Predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quantitative determination of total iron	same
Reagent components	Ferene® (chromophore) Thiourea (prevent Cu interference) Ascorbic acid (reducing agent)	same
Measurement method	Bi-chromatic endpoint measurement (600 and 700 nm)	same
Calibration	linear calibration	same
Assay Range	0 to 1,000 µg/dL	same
Sample Types	Serum and Heparin plasma	same
Standardization	NIST SRM 937	same

Differences		
Item	**Device**	**Predicate**
Sample Volume	20uL	40uL
Calibration Scheme	2 levels in duplicate	3 levels in triplicate

J. Standard/Guidance Document Referenced
1. Guidance;
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
A New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications
Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable - Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA Staff

2. Standards;
Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied (15223), General, ISO
Medical devices - Application of risk management to medical devices (14971:2000) General, ISO
Stability Testing of In Vitro Diagnostic Reagents (13640), InVitro, CEN
Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (GP 22-A), InVitro, NCCLS
Interference Testing in Clinical Chemistry; Approved Guideline (EP 7-A), InVitro, NCCLS
Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition (EP5-A2),InVitro, CLSI
Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (EP09-A2), InVitro, NCCLS

K. Test Principle:
The automated Dimension Vista™ IRON method is an adaptation of direct iron assays using the chromophore Ferene ® . Under acidic conditions, iron (Fe+++) bound to the protein transferrin is released. In the presence of the reducing agent ascorbic acid, (Fe+++) is reduced to (Fe++). (Fe ++) forms a blue complex with 3-(2-pyridyl)-5,6-bis-2-(5-furyl sulfonic acid)-1,2,4-triazine, disodium salt (Ferene®). The absorbance of the complex, measured using a bichromatic (600, 700 nm) endpoint technique, is directly proportional to the concentration of transferrin-bound iron in the serum.

L . Comments on Substantial Equivalence/Conclusion:
The performance testing according to the verification and validation test protocols demonstrate that the Dimension Vista™ IRON Flex® reagent cartridge is substantially equivalent to the designated predicate device.

510(k) Summary for the
Dimension Vista™ IRON Calibrator

A. 510(k) Number:

B. Analyte: Iron Calibrator

C. Type of Test: Calibrator Material

D. Applicant:
Manufacturer: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101

Contact: Andrea M. Tasker, Regulatory Affairs and Compliance Manager
(302) 631-9454

Date of Preparation: June 23, 2006

E. Proprietary and Established Names:
Dimension Vista™ Iron Calibrator

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – CALIBRATOR

2. Classification: Class II

3. Product Code: JIS - CALIBRATORS, PRIMARY

4. Panel: CLINICAL CHEMISTRY

G. Intended Use:
1. Intended use(s):

The IRON Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the IRON method for the Dimension Vista ™ system.

2. Indication(s) for use:

The IRON Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the IRON method for the Dimension Vista ™ system.

3. Special condition for use statement(s): none

4. Special instrument Requirements: none

H. Device Description:

The Dimension Vista™ Iron Calibrator is an aqueous solution of iron wire dissolved in a dilute solution of HCl. The kit contains three glass screw top vials, 1.0 mL each, of the Calibrator A (1075 ug/dL).

. Substantial Equivalence Information:

1. Predicate Device: Dimension® Iron Calibrator (DC85)

2. Predicate K Number(s): K060266

3. Comparison with Predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	To calibrate the iron method	same
Traceability	NIST SRM 937 (NIST SRM: National Institute of Standards and Technology- Standard Reference Material)	same
Matrix	Aqueous solution of iron wire dissolved in a dilute solution of HCl	same

Differences		
Item	**Device**	**Predicate**
Vial Type	Glass screw top vial 1.0 mL each	Glass Ampule, 1.2 mL each
Target Concentrations for Calibration	Level 1 (Sytem Water) 0 ug/dL Leve 2 - 1075 ug/dL	Level 1 (Sytem Water) 0 ug/dL Level 2 -50 ug/dL Level 3 - 1075 ug/dL

J. Standard/Guidance Document Referenced:

1. Guidance;
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
A New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications

2. Standards;
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Medical devices - Application of risk management to medical devices (14971:2000) General, ISO
Stability Testing of In Vitro Diagnostic Reagents (13640), InVitro, CEN
Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (GP 22-A), InVitro, NCCLS

K. Test Principle:
The Dimension Vista™ Iron Calibrator is an in vitro diagnostic product intended to be used to calibrate the Dimension Vista™ IRON method for the Dimension Vista™ system.

L . Comments on Substantial Equivalence/Conclusion:
The performance testing according to the verification and validation test protocols demonstrate that the Dimension Vista™ Iron Calibrator is substantially equivalent to the designated predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 7 2006

Ms. Andrea M. Tasker
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Glasgow Business Community
PO Box 6101, MS 514
Newark DE 19714-6101

Re: k061793
Trade/Device Name: Dimension Vista™ IRON Flex® reagent cartridge
Dimension Vista™ IRON Calibrator
Regulation Number: 21 CFR§862.1410
Regulation Name: Iron (non-heme) test system
Regulatory Class: Class I
Product Code: JIY, JIT
Dated: July 21, 2006
Received: July 24, 2006

Dear Ms. Tasker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known):

Device Name: K061793
Dimension Vista ™ IRON Flex® reagent cartridge

Indications for Use:

The iron method for the Dimension Vista ™ system is an *in vitro* diagnostic test intended to quantitatively measure iron in human serum and plasma. Iron measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia and other disorders of iron metabolism.

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Prescription Use ___X___ **AND/OR** **Over-the-counter Use _____**
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K061793

Indications For Use Statement

510(k) Number (if known):

Device Name: K061793
Dimension Vista™ IRON Calibrator

Indications for Use:

The IRON Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the IRON method for the Dimension Vista™ system.

Prescription Use ___X___ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K061793